

K-12 Schools COVID-19 White House Antigen Point-of-Care Test Program



Background

The White House Point of Care (POC) testing program supports ongoing COVID-19 testing and *Test to Stay (TTS) programs in K-12 schools. These rapid antigen tests can be used for people who have symptoms or who are close-contacts of someone with COVID-19. They can also be used as part of a screening testing program to identify infections in people without symptoms. By promptly identifying members of the school community who may be infectious to others, the school can quickly isolate cases, identify close contacts who need to quarantine, and identify clusters of cases. Testing is one of several mitigation strategies to reduce the spread of COVID-19 in schools and create a safer learning environment. This testing program is optional.

*Test to Stay (TTS) is a program that allows students and staff who are not <u>up to date</u> on recommended COVID-19 vaccines to avoid quarantine and stay in school through testing. See <u>DOH</u> Guidance for Test to Stay (TTS) in K-12 Schools for further information.

Testing is recommended for:

- Students and staff who exhibit symptoms of COVID-19 while in school and before they are sent home.
- Students and staff who have been exposed to someone with COVID-19.
- Students who are not <u>up to date</u> with recommended COVID-19 vaccines when community levels are at medium or high.
- Teachers and staff who are not <u>up to date</u> on recommended COVID-19 vaccines, regardless of community level.
- Schools unable to consistently implement multiple layered mitigation measures.
- Students who are not <u>up to date</u> on recommended COVID-19 vaccines before engaging in high-risk athletics, competitions, or extracurricular events.
- To keep students who are close contacts in school instead of quarantine as part of a TTS program.

Who can use these tests?

The Abbott BinaxNOW test for SARS-CoV-2 is categorized as a CLIA waived test. While these tests can be administered in a school setting, the site must comply with State and Federal requirements for testing, and testing must be administered by trained staff.

How are tests administered?

The student or staff who is symptomatic or part of a group that is designated for screening testing will receive a free BinaxNOW rapid COVID-19 test. The person's identity and test kit ID will be recorded to associate the test result with the person.

Specimens are collected using a swab, like a Q-Tip, placed inside the tip of the nose and rotated. Adults and children physically able to do so may self-swab under the direction of a staff who has been trained on the process for specimen collection for BinaxNOW. The trained staff can collect the specimen if the person being tested is unable to self-swab. Trained staff will then perform the test and read the results.

POC Testing Checklist

- ✓ Certificate of Waiver: The site has received a CLIA Certificate of Waiver OR has identified an entity with a CLIA. See Ouick Guide to CLIA Certification for COVID-19 Testing in Schools.
- ✓ **Provider Order:** The site has acquired a signed standing order for COVID-19 testing with the Abbott BinaxNOW from a physician or authorized person.
- ✓ Training Requirements: The site has ensured that all staff members who will be administering Abbott BinaxNOW test kits have reviewed the following training materials: <u>Abbot BinaxNOW Overview</u> <u>Collecting Nasal Swab Video</u>
- ✓ PPE: The site has acquired an adequate supply of PPE and will be able to procure additional PPE as needed. Staff not involved in specimen collection should wear at a minimum gloves and disposal surgical masks. For staff involved in specimen collection, gloves, N95 masks, gowns, and face shields or safety glasses are advised.
- ✓ **Storage:** The site has identified a temperature stable location to store test kits. Test kits must be stored at temperatures between 35.6°F (2°C) and 86° F (30°C). See <u>Storage</u>.
- ✓ **Medical Waste Management:** The site has a mechanism to safely dispose of used testing material. See <u>Medical Waste Management</u>.
- ✓ **Reporting Requirements:** The site has trained all necessary staff on how to report test results to the DOH. See <u>COVID-19 Laboratory Reporting</u>.
- ✓ **Communication Plan:** There is a plan to educate students and their families about the availability of testing.

Ongoing Requirements

- Testing personnel will adhere to the written instructions for use provided by the manufacturer in the test package insert.
- The site will provide DOH information about test administrators and testing locations if they change from the time a CLIA Waiver is approved. Contact Diane Kumashiro at doh.hawaii.gov with these changes.
- The site will acquire informed consent for all individuals participating in testing.
- The site must identify an "authorized person" who is qualified to order, receive and interpret laboratory test results. This could be a physician, osteopath, dentist, veterinarian, naturopathic physician, podiatrist, advanced practice nurse practitioner, optometrist, physician assistant under supervision of a licensed physician, pharmacist in collaboration with a licensed physician, chiropractor, or other health care practitioner. They must be licensed in the State of Hawaii. They are not required to be at the site but should assist in guiding the school with the waiver, testing, and reporting and should visit the site at least twice a year.

Storage

In accordance with the BinaxNOW test kit instructions for use, test kits must be stored at temperatures between (35.6°F/2°C) and (86° F/30°C). The instructions for use require that test components (antigen card and buffer) are at room temperature (59°F/15°C) and (86°F/30°C) when performing the test. Set out test kits 30-60 minutes prior to use if refrigerated. Test kits should not be stored in a warm place or in direct sunlight.

Test Kit Dimensions: 9.125" L x 0.938" D x 5.063" H

Small box of 40 test kits - 6 inches by 12 inches

Large box of 400 test kits (10 boxes of 40 kits) - 1x2x2. 1 foot tall, 2 feet wide by 2 feet deep

Medical Waste Management

Infectious waste should be immediately discarded.

1. Discard waste into a plastic trash bag.



2. Tie or tape to close.



3. Discard bag into municipal waste, such as an outdoor dumpster or trash bag.



Frequently Asked Questions

Are tests through this program only available for students, faculty and staff? Could they be offered to families? This program aims to support and sustain screening and TTS programs in schools. School testing includes students, staff, and volunteers. It can be used to supplement other testing programs such as Operation Expanded Testing through Color/Perkin-Elmer.

Can multiple tests be administered to a group who is practicing distancing and masking? Yes. Multiple students can test at the same time as long as the mitigation strategies that are outlined in the COVID-19 Comprehensive
Guidance for K-12 Schools are followed.

Can the individual collect their own sample for testing? The specimen collection can be self-administered but can be done by trained staff if needed. See <u>Collecting Nasal Swab Video</u>.

Is the POC antigen test preferred over the Color test that is a PCR test? Both POC antigen tests and PCR tests are good testing options. The POC antigen test allows you to receive your results on-site and within 15-20 mins. PCR tests are done in a laboratory and result are returned in 1-4 days.

Would a student's guardian need to complete a consent form for their child to participate in testing? Written consent should be obtained for testing. If a consent has been obtained for another testing program (such as Color), your administration should determine if a separate consent is required. Some schools have chosen to adopt an optout system where families are informed about testing and may submit a written opt-out form if they do not want their child to participate.

What is the DOH's suggestion on how these tests would be most beneficial to schools? Testing is an important COVID-19 mitigation strategy for schools. See <u>Rockefeller Foundation's playbook</u> which provides guidance to help design and implement effective testing programs in schools.

If a person tests positive using an antigen test, would they need to get a PCR test to confirm the positive result? No. A person who receives a positive result from a POC antigen test is considered to have COVID-19 and should isolate per DOH guidelines and encourage their close-contacts to seek out testing.

Could our school health aide oversee testing? A school health aide or other school staff can undergo training and manage the day-to-day activities of school testing. They must operate under the oversight of the person authorized to perform waived COVID-19 testing at the school site. The "authorized person" is not required to be at the site but should assist in guiding the school with the waiver, testing, and reporting and should visit the site at least twice a year.

How often are tests ordered and what is the expected delivery time? Will the tests be delivered to our school? As of March 1st, an order will be placed every four weeks and schools should order a four-week supply of test kits. When tests are received, they are distributed to a centralized site for pick-up and through the Hawaii Keiki nursing program operating in some public schools.

What is the estimated fee for a CLIA waiver? The fees associated with this process are: \$180 CMS application fee, and \$100 permit initial fee + \$75 annual fee. This certificate can be put on hold with no fees incurred during that time and turned back on again when needed.

Additional Resources

Consent Form Example

See <u>page 7</u> for an example of a consent form that schools may use to acquire informed consent for individuals participating in testing.

*This is not an official form and should be reviewed by your school and modified as needed.

Quick Start Guide to CLIA Certification for COVID-19 Testing in Schools

The completed CLIA form should be emailed to:

Hawaii Department of Health CLIA Program

Email: doh.ohcamco@doh.hawaii.gov

Phone: (808) 692-7420

COVID-19 Laboratory Reporting

For COVID-19 laboratory reporting, <u>ALL</u> results (positive, negatives, inconclusive, etc.) need to be reported to the State of Hawaii, Department of Health via the <u>Hawaii Lab</u> <u>Reporting Portal</u> within 24-hours from test completion per <u>CARES Act Section 18115</u>.

School should also notify the Hawai'i State Department of Health of **positive cases** within 24 hours via the online case reporting tool that DOH has requested that your school use. If you have questions regarding the online case reporting tool see the <u>contact information for school administrators</u> on page 2.

References

North Carolina Department of Health and Human Services. (n.d.). K-12 COVID-19 antigen testing application packet. Retrieved February 2, 2022, from https://covid19.ncdhhs.gov/media/946/open

South Dakota Department of Health. (n.d.). Abbott BinaxNOW COVID-19 antigen testing in South Dakota's K-12 schools. Retrieved February 2, 2022, from https://doe.sd.gov/coronavirus/documents/AbbottBinaxNOW.pdf

Consent Form Example

TO BE COMPLETED BY PARENT, GUARDIAN OR ADULT STUDENT				
Parent/Guardian OR Adult Student Information				
You will be notified with test results either via cell phone or email, or both.				
Print Name:				
Phone Number: Note: results will be texted to this cell #				
Email Address:				
Student Information				
Student Name:				
Street Address:		City:		
Zip Code:				
School Name:		Grade:		
Age:				
	CONSENT			
A. I give authorization to conduct collection and testing of my child or me (if student age 18 or older) for COVID-19 by nasal swab. B. I acknowledge that a positive test result is an indication that my child or me (if student age 18 or older), must self-isolate and continue wearing a mask or face covering as directed to avoid infecting others. C. I understand the school system is not acting as my child's medical provider, this testing does not replace treatment by my child 's medical provider, and I assume complete and full responsibility to take appropriate action with regards to my child's test results. I agree I will seek medical advice, care and treatment from my child's medical provider if I have questions or concerns, or if their condition worsens. D. I understand that, as with any medical test, there is the potential for a false positive or false negative COVID-19 test result. E. I, the undersigned, have been informed about the test purpose, procedures, possible benefits and risks, and I have received a copy of this Informed Consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask additional questions at any time. I voluntarily agree to this testing for COVID-19. F. I understand that my personal information and test result will be shared with the school to guide decisions on health, safety, and/or returning to school, as well as with the Hawaii Department of Health.				
Signature of Parent/ Guardian:			Date:	
Signature of Student: (if age 18 or over or otherwise authorized to consent)			Date:	